

Application No. 10/762,421  
Amendment dated June 19, 2008  
Reply to Office Action of December 19, 2008

Docket No.: CDSI-P01-040

**REMARKS**

Claims 1-14, 16-18 and 20-21 constitute the pending claims in the present application. The Examiner has withdrawn claims 4-9 and 11-13. Claims 1, 2, 14 and 18 have been amended in response to the Examiner's rejection. Support for these amendments can be found, for example, in the specification on p. 11, lines 20-27. Applicants assert that these amendments are fully supported by the specification and add no new matter.

Applicants respectfully request reconsideration in view of the foregoing amendments and following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

Withdrawal of rejection based on 35 U.S.C. 112. Applicants acknowledge with appreciation the withdrawal of the rejection to claim 14 for indefiniteness.

Rejection based on 35 U.S.C. 103(a). The Office has maintained its rejection of claims 1-3, 10, and 14-17 under 35 U.S.C. 103(a) as being obvious over Smith et al. (U.S. Patent No. 5,378,475) ("Smith") in view of Wong et al. (U.S. Patent No. 6,331,313) ("Wong"). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

Smith discloses the method and device for treating a mammalian organism in order to obtain a desired local or systemic physiological or pharmacological effect wherein, the device includes an inner core or reservoir comprising the effective agent; a first coating layer, which is essentially impermeable to the passage of the effective agent; and a second coating layer, which is permeable to the passage of the effective agent. The first coating layer covers the inner core; however, at least a small portion of the inner core is not coated with the first coating layer. The second coating layer essentially completely covers the first coating layer and the uncoated portion of the inner core. (abstract, U.S. 5,378,475).

Wong discloses controlled release devices which have a core comprising a drug. In addition, a polymeric outer layer which is substantially impermeable to the entrance of an environmental fluid and substantially impermeable to the release of the drug during a delivery period covers the core. Drug release is effected through an orifice in the outer layer (abstract, U.S. 6,331,313). Wong does not teach a device that includes a matrix material that is admixed with the drug to inhibit or prevent decomposition, as recited in the pending claims.

Application No. 10/762,421  
Amendment dated June 19, 2008  
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Docket No.: CDSI-P01-040

Conversely, pending independent claims 1 and 2 and dependent claims 3 and 10 recite a sustained release drug delivery device adapted for implantation in or adjacent to the eye of a patient, the drug delivery device comprising: (i) an inner drug core comprising a carbonic anhydrase inhibitor; (ii) a first coating layer; and (iii) one or more additional coating layers that are permeable to the passage of the carbonic anhydrase inhibitor and *comprise a carbonic anhydrase inhibitor that is the same or different as the carbonic anhydrase inhibitor of the inner drug core*. Neither Smith or Wong, either alone or in combination, teach or suggest a second layer *comprising anything*, let alone a carbonic anhydrase inhibitor that is the same or different than the carbonic anhydrase inhibitor of the inner drug core. In fact, Wong is silent with regard to any other layer beyond its first polymer layer.

Independent claim 14 and dependent claims 15-17 recite a sustained release drug delivery device adapted for insertion in or adjacent to the eye of the patient, the drug delivery device comprising: (i) an inner drug core comprising a carbonic anhydrase inhibitor; (ii) a layer that is partially or substantially permeable to the passage of the carbonic anhydrase inhibitor and *comprise a carbonic anhydrase inhibitor that is the same or different as the carbonic anhydrase inhibitor of the inner drug core*. Neither Smith or Wong teach or suggest a layer comprising anything, let alone a carbonic anhydrase inhibitor.

While both Smith and Wong recite an inner core containing an active agent covered by a polymeric layer, neither teaches a layer that comprises a carbonic anhydrase inhibitor that is the same or different as the carbonic anhydrase inhibitor of the inner drug core. Thus, because Smith in view of Wong does not teach or suggest all of the limitations recited in the pending claims, Applicants submit that the skilled artisan would have no expectation of success in modifying Smith as presently claimed. Accordingly, Applicants request that the Examiner withdraw the above obviousness rejection.

Rejection based on 35 U.S.C. 103(a). The Office has maintained its rejection of claims 18-21 under 35 U.S.C. 103(a) as being obvious over Chen et al. (U.S. Patent No. 5,902,598) ("Chen") in view of Wong et al. (U.S. Patent No. 6,331,313) ("Wong"). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

Chen discloses a method and device for sustained drug release that includes an inner core reservoir of effective agent, a first coating layer permeable to the passage of the effective agent,

Application No. 10/762,421  
Amendment dated June 19, 2008  
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Docket No.: CDSI-P01-040

a second impermeable coating layer, and a third coating layer permeable to the passage of the effective agent (abstract, U.S. 5,902,598). Chen does not teach or suggest a device that contains a layer which *includes a carbonic anhydrase inhibitor that is the same or different as the carbonic anhydrase inhibitor of the inner core* as recited in pending claims 18 and 20-21. In fact, Chen is silent with regard to any substance within either its impermeable coating layer or its permeable coating layer.

Furthermore, as discussed above, Wong also does not teach a device which includes an outer layer that comprises a carbonic anhydrase inhibitor that is the same or different as the carbonic anhydrase inhibitor of the inner core. In fact, like Chen, Wong is silent with regard to its layer containing anything, let alone a carbonic ahydrase inhibitor. Thus, because Chen in view of Wong does not teach or suggest all of the limitations of the pending claims, Applicants submit that the skilled artisan would have no expectation of success in modifying Chen as presently claimed. Accordingly, Applicants request reconsideration of the above obviousness rejection.

Co-pending applications. Lastly, Applicants, in accordance with the on-going duty of disclosure, would like to direct the Examiner's attention to a Final Office Action issued on January 4, 2008 in co-pending U.S. application 10/762,439.

Application No. 10/762,421  
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Docket No.: CDSI-P01-040

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617.951.7000. A three-month petition for extension of time and authorization of the prescribed fee are being filed herewith. Please charge any further fees due or credit any overpayments to our Deposit Account No. 18-1945, under Order No. CDSI-P01-040 from which the undersigned is authorized to draw.

Dated: June 19, 2008

Respectfully submitted,

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